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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/557,907 | 04/21/00 | HORTON | H 1530.0060004 |
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HM12/1022  
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EXAMINER

WILSON, M

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

10/22/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/557,907

Applicant(s)

HORTON ET AL.

Examiner

Michael Wilson

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 51,57,65,76,88 and 95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50,52-56,58-64,66-75,77-87,89-94 and 96-103 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the burden to search DNA and mRNA would not be undue. This is not found persuasive because the method of delivering DNA to a host to treat cancer would indeed require a separate search than the method of delivering mRNA to a host to treat cancer. Furthermore, the purpose of delivering DNA is to express protein while the purpose of delivering mRNA is to prevent protein production. Therefore, Groups I and II are patentably distinct. The requirement is still deemed proper and is therefore made FINAL. Claims 51, 57, 65, 76, 88 and 95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Upon further consideration, claims 1-50, 52-56, 58-64, 66-75, 77-87, 89-94 and 96-103 require further restriction.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-35, 38-50, 66-75 and 77-87 drawn to a method of treating cancer using a plasmid encoding a cytokine that is not formulated in a composition comprising sodium phosphate dissolved in an aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM, classified in class 514, subclass 44.

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- II. Claims 36, 37, 52-56, 58-64, ~~66-87~~, 89-94 and 96-103 drawn to compositions comprising a polynucleotide and sodium phosphate dissolved in an aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM and methods of using such compositions, classified in class 435, subclass 320.1 and others.
2. The inventions are distinct, each from the other because of the following reasons:
- Groups I and II represent different inventive concepts because compositions comprising a polynucleotide and sodium phosphate dissolved in an aqueous solution at a molar concentration ranging from about 20 mM to about 300 mM are not required to treat cancer and methods of treating cancer do not require such compositions. The burden required to search the subject matter encompassed by both groups would be undue. For example, the search required for claim 90 is not required for claim 1. The method of treating cancer (claim 1) does not require a polynucleotide and sodium phosphate at the concentrations recited. The compositions of polynucleotide and sodium phosphate (claim 90) does not have to be used to treat cancer as it can also be used to transfect cells *in vitro*. Therefore, the inventive concepts are patentably distinct and separate and restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

A handwritten signature in black ink, appearing to read "Mic", followed by a horizontal line.